

claims, as requested, whereas **Exhibit B** shows the changes with brackets and underlining. The claims in each have been labeled as "(Amended)" or "(New)", where appropriate.

II. Claims Rejoined

The Action at page 2 confirms that claims 20, 38 and 39 have been maintained in the case, examined and have been allowed. The summary page of the Action, which suggests that claims 20, 38 and 39 are withdrawn from consideration is therefore an error of oversight.

III. Claims Allowed

The Action at pages 2 and 3 states that claims 1-47 and 49-68 are directed to an allowable product¹ and are free of the prior art of record. The summary page of the Action, which suggests that certain of these claims are rejected or objected to, is therefore also an error of oversight.

Although the Action states that claims 1-47 and 49-68 are free of the prior art of record, it appears that a copy of the Examiner's initialed PTO Form-1449 listing the references timely made of record by the Applicants has been omitted. Applicants therefore respectfully request that a copy be included in the Notice of Allowance to complete the record.

IV. Support for the Claims

Support for the amended and new claims exists in the pending claims, and also throughout the original specification as filed. Although additional fees should not be required for the new claims, any small entity fees deemed necessary for their introduction should be deducted from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/4100.002000.

Claim 1 has been revised as a precaution to even more clearly set forth that the porous nature of the structural matrix applies to the alginate and modified alginate matrices of element (b), in addition to the porous polymer of element (a). In addition to claim 1 itself,

further support for the "porous" alginate matrices exists in claims 17 and 18 (see part (d), in particular), supplemented throughout the specification.

Claims 13, 48, 66 and 68 have also been amended as a precaution to even more clearly define the alginate and modified alginate matrices as "porous" alginate matrices, and are supported as described above for claim 1.

New claims 102 and 103 simply separately recite a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer, listed in the alternative in claims 66 and 68, from which they depend and are supported thereby.

It will therefore be understood that no new matter is included within any of the amended or new claims.

V. Rejection of Claim 48 Under 35 U.S.C. § 102(b)

The only rejection in the case is that of claim 48 under 35 U.S.C. § 102(b) as allegedly being anticipated by Wheatley *et al.*, U.S. Patent No. 4,933,185 ("Wheatley"). Although Applicants respectfully traverse, the Action's concerns are addressed.

The Action at page 3 indicates that Wheatley does not anticipate any of claims 1-47 or 49-68 as Wheatley only concerns compositions that are not porous structures. Without acquiescing with the rejection in any way, and in order to progress the application to allowance as timely and cost-effectively as possible, Applicants elect to clarify claim 48 to even more clearly recite "porous" alginate or modified alginate matrices, in accordance with the allowed claims.

The Examiner's understanding of Applicants' intended meaning of the porous nature of the structural matrices recited in claim 1, and the other allowed claims, is appreciated. However,

¹Allowed claims 1-47 and 49-68 include certain method claims as well as product claims.

in an abundance of caution, Applicants also elect to even more clearly define that the porosity of the structural matrices in claims 1, 13, 48, 66 and 68 applies to the alginate and modified alginate matrices.

Therefore, the claims as a whole now even better accord with the Examiner's assessment of allowable subject matter.

The rejection of claim 48 under 35 U.S.C. § 102(b) is also overcome and should be withdrawn.

VI. Conclusion

This is a complete response to the referenced Official Action. In conclusion, Applicants submit that, in light of the claims already allowed and the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested. Should Examiner Kaushal have any questions or comments, a telephone call to the undersigned Applicants' representative is earnestly solicited.



Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Shelley P.M. Fussey".

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EXHIBIT A
PENDING CLAIMS
U.S. SERIAL NO. 09/442,542 (4100.002000; UM 1522p1)

1. (Amended) A composition comprising at least a first nucleic acid segment in association with a structural matrix, wherein:
 - (a) at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer; or
 - (b) at least a portion of said structural matrix is a porous alginate or modified alginate matrix.
2. The composition of claim 1, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.
3. The composition of claim 2, wherein at least a portion of said structural matrix is comprised of a porous polymer that has an open pore structure.
4. The composition of claim 3, wherein at least a portion of said structural matrix is comprised of a porous polymer that has an interconnected pore structure.
5. The composition of claim 2, wherein said structural matrix consists essentially of a porous polymer that has an open pore structure.
6. The composition of claim 2, wherein said structural matrix comprises at least a first matrix portion comprised of said porous polymer integrally connected to at least a second matrix portion comprised of an impermeable polymer.
7. The composition of claim 6, wherein said at least a first matrix portion is comprised of a porous polymeric material that has a substantially uniform open pore structure, and wherein said at least a second matrix portion is comprised of the same polymeric material in a form that lacks an open pore structure.
8. The composition of claim 2, wherein said structural matrix is a biocompatible matrix.

9. The composition of claim 2, wherein said structural matrix is a biodegradable matrix.
10. The composition of claim 2, wherein said structural matrix is a biocompatible and biodegradable matrix.
11. The composition of claim 2, wherein at least a portion of said structural matrix is comprised of a lactic acid polymer, glycolic acid polymer or lactic acid/glycolic acid copolymer matrix.
12. The composition of claim 11, wherein at least a portion of said structural matrix is comprised of a lactic acid/glycolic acid (PLGA) copolymer matrix.
13. (Amended) The composition of claim 1, wherein at least a portion of said structural matrix is a porous alginate or modified alginate matrix.
14. The composition of claim 13, wherein at least a portion of said structural matrix is a modified alginate matrix that comprises at least one alginate chain section bonded to at least one molecule that mediates cellular interactions.
15. The composition of claim 14, wherein at least a portion of said structural matrix is a modified alginate matrix that comprises at least one alginate chain section bonded to at least one cellular interaction molecule selected from the group consisting of cell adhesion molecules, cell attachment peptides, proteoglycan attachment peptide sequences, proteoglycans, cell adhesion polysaccharides, growth factors and cell adhesion enzymes.
16. The composition of claim 15, wherein at least a portion of said structural matrix is a modified alginate matrix that comprises at least one alginate chain section bonded to at least one cellular interaction molecule selected from the group consisting of an RGD peptide, fibronectin, vitronectin, Laminin A, Laminin B1, Laminin B2, collagen 1 and thrombospondin.
17. The composition of claim 13, wherein at least a portion of said structural matrix is a modified alginate matrix prepared by a method comprising:
 - (a) providing a solution of a hydrogel-forming material and a surfactant;
 - (b) mixing said solution in the presence of a gas to form a stable foam;

- (c) exposing said stable foam to conditions or agents that result in gelling of the hydrogel-forming material and in the generation of gas bubbles therein; and
- (d) exposing the hydrogel containing gas bubbles to a vacuum to release the gas and form the hydrogel material having macroporous open pore porosity.

18. The composition of claim 13, wherein at least a portion of said structural matrix is a modified alginate matrix prepared by a method comprising:

- (a) providing a solution of a hydrogel-forming material, a surfactant and a gas-generating component, wherein said solution is capable of being mixed in the presence of a gas to incorporate the gas in the solution and form a stable foam;
- (b) mixing said solution in the presence of a gas to form a stable foam;
- (c) exposing said stable foam to conditions or agents that result in gelling of the hydrogel-forming material and to conditions or agents that result in generation of gas from the gas-generating component, to form a hydrogel containing gas bubbles therein; and
- (d) exposing said hydrogel containing gas bubbles therein to a vacuum to release the gas and to form the hydrogel material having macroporous open pore porosity.

19. The composition of claim 1, wherein said nucleic acid segment is a DNA molecule.

20. The composition of claim 1, wherein said nucleic acid segment is an antisense nucleic acid molecule or a ribozyme.

21. The composition of claim 1, wherein said nucleic acid segment is comprised within a plasmid or a recombinant expression vector.

22. The composition of claim 21, wherein said nucleic acid segment is operatively positioned downstream from a promoter within a recombinant viral expression vector.

23. The composition of claim 22, wherein said nucleic acid segment is operatively positioned downstream from a promoter within a recombinant adenovirus, a recombinant adeno-associated virus (AAV) or a recombinant retrovirus.

24. The composition of claim 21, wherein said nucleic acid segment encodes a protein or polypeptide.

25. The composition of claim 24, wherein said nucleic acid segment encodes a marker protein.

26. The composition of claim 24, wherein said nucleic acid segment encodes a protein or polypeptide that stimulates a bone progenitor cell when expressed in said cell.

27. The composition of claim 24, wherein said nucleic acid segment encodes a protein or polypeptide that stimulates a wound healing fibroblast, granulation tissue fibroblast or repair cell when expressed in said cell.

28. The composition of claim 24, wherein said nucleic acid segment encodes an antigenic or immunogenic protein or polypeptide that stimulates an immune response when expressed by an antigen presenting cell.

29. The composition of claim 24, wherein said nucleic acid segment encodes a cytotoxic or apoptosis-inducing protein or polypeptide that induces cell death upon expression in a cell.

30. The composition of claim 24, wherein said nucleic acid segment encodes a transcription or elongation factor, cell cycle control protein, kinase, phosphatase, DNA repair protein, oncogene, tumor suppressor, angiogenic protein, anti-angiogenic protein, immune response stimulating protein, cell surface receptor, accessory signaling molecule, transport protein, enzyme, anti-bacterial or anti-viral protein or polypeptide.

31. The composition of claim 24, wherein said nucleic acid segment encodes a hormone, neurotransmitter, growth factor, growth factor receptor, interferon, interleukin, chemokine, cytokine, colony stimulating factor or chemotactic factor protein or polypeptide.

32. The composition of claim 31, wherein said nucleic acid segment encodes a growth hormone (GH) protein or polypeptide, a parathyroid hormone (PTH) protein or polypeptide, a PTH1-34 polypeptide or a bone morphogenetic protein (BMP) protein or polypeptide.

33. The composition of claim 32, wherein said nucleic acid segment encodes a BMP-2A, BMP-2B, BMP-3, BMP-4, BMP-5, BMP-6, BMP-7 or BMP-8 protein or polypeptide.

34. The composition of claim 31, wherein said nucleic acid segment encodes a transforming growth factor- α (TGF- α), TGF- β 1 or TGF- β 2 protein or polypeptide, a latent TGF β binding protein (LTBP) protein or polypeptide, an activin/inhibin protein or polypeptide, a fibroblast growth factor (FGF), a granulocyte/macrophage colony stimulating factor (GMCSF), an epidermal growth factor (EGF), a platelet derived growth factor (PDGF), an insulin-like growth factor (IGF) or a leukemia inhibitory factor (LIF).

35. The composition of claim 24, wherein said nucleic acid segment encodes a human protein or polypeptide.

36. The composition of claim 1, comprising at least a first and second nucleic acid segment.

37. The composition of claim 1, comprising a plurality of nucleic acid segments.

38. The composition of claim 1, further comprising a population of cells.

39. The composition of claim 38, wherein at least a portion of said nucleic acid segment is taken up by the cells comprised within said composition.

40. The composition of claim 1, prepared by admixing at least a first nucleic acid segment with said structural matrix.

41. The composition of claim 2, prepared by a process that comprises leaching out the particulate material from a composition comprising a gas foamed polymeric material, at least a first nucleic acid segment and a leachable particulate material.

42. The composition of claim 2, prepared by a process that comprises the steps of:

- (a) preparing an admixture comprising at least a first nucleic acid segment, particles capable of forming a polymeric structure and a leachable particulate material;
- (b) subjecting said admixture to a gas foaming process to create a porous polymeric structure that comprises said at least a first nucleic acid segment and said leachable particulate material; and

- (c) subjecting said porous polymeric structure to a leaching process that removes said leachable particulate material from said porous polymeric structure, thereby producing a polymeric structure of additional porosity that comprises said at least a first nucleic acid segment.

43. The composition of claim 42, wherein said admixture comprises said at least a first nucleic acid segment, beads or microspheres capable of forming a polymeric structure and said leachable particulate material.

44. The composition of claim 43, wherein said at least a first nucleic acid segment is incorporated within said beads or microspheres prior to said admixing or gas foaming steps.

45. The composition of claim 42, wherein said leaching process is conducted *in vitro* by subjecting said porous polymeric material to a leaching agent.

46. The composition of claim 42, wherein said leaching process is conducted *in vivo* by exposing said porous polymeric material to body fluids.

47. A composition comprising at least a first nucleic acid segment in non-covalent association with a structural matrix, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

48. (Amended) A composition comprising at least a first nucleic acid segment in non-covalent association with a structural, porous alginate or modified alginate matrix.

49. A composition comprising at least a first nucleic acid segment in association with a structural matrix, said structural matrix comprising at least a first matrix portion comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer, wherein said first matrix portion is integrally connected to a second matrix portion comprised of an impermeable polymer.

50. The composition of claim 49, wherein said first and second matrix portions are comprised of the same polymeric material, separately fabricated to form a first, porous polymer having a uniform open pore structure and a second, impermeable polymer lacking an open pore structure.

51. The composition of claim 49, wherein said first and second matrix portions are comprised of different polymeric materials.

52. An admixture, comprising at least a first nucleic acid segment; beads or microspheres of a polymer capable of forming a gas-foamed polymeric structure; and a leachable particulate material.

53. The admixture of claim 52, wherein said at least a first nucleic acid segment is incorporated within said beads or microspheres.

54. A method for making a structural matrix-nucleic acid composition, comprising providing at least a first nucleic acid segment to a structural matrix, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

55. The method of claim 54, comprising leaching out the particulate material from a composition comprising a gas foamed polymeric material, at least a first nucleic acid segment and a leachable particulate material.

56. The method of claim 55, comprising the steps of:

- (a) preparing an admixture comprising at least a first nucleic acid segment, particles of a polymeric material capable of forming a gas foamed polymeric structure and a leachable particulate material;
- (b) subjecting said admixture to a gas foaming process to create a porous polymeric structure that comprises said at least a first nucleic acid segment and said leachable particulate material; and
- (c) subjecting said porous polymeric structure to a leaching process that removes said leachable particulate material from said porous polymeric structure, thereby producing a polymeric structure of additional porosity that comprises said at least a first nucleic acid segment.

57. The method of claim 56, wherein said admixture is prepared by first incorporating said at least a first nucleic acid segment within said particles of a polymeric material and then admixing with said leachable particulate material.

58. The method of claim 57, wherein said admixture is prepared by first incorporating said at least a first nucleic acid segment within polymer beads or microspheres and then admixing with said leachable particulate material.

59. The method of claim 56, wherein the gas foaming process of step (b) comprises subjecting said admixture to an elevated pressure atmosphere of an inert gas in a manner effective to dissolve said gas into said polymeric material, and subjecting the gas-dissolved polymeric material to thermodynamic instability in a manner effective to cause nucleation and growth of gas pores sufficient to produce a continuous matrix of polymeric material that comprises said at least a first nucleic acid segment and said leachable particulate material.

60. The method of claim 59, wherein said thermodynamic instability is created by reducing said elevated pressure atmosphere.

61. The method of claim 56, wherein said leachable particulate material is a water-soluble leachable particulate material.

62. The method of claim 61, wherein said leachable particulate material is a salt, sugar or sugar alcohol.

63. The method of claim 62, wherein said leachable particulate material is NaCl, trehalose, glucose, sucrose or mannitol.

64. The method of claim 56, wherein said leaching process is conducted *in vitro* by contacting said porous polymeric material with a leaching agent.

65. The method of claim 56, wherein said leaching process is conducted *in vivo* by exposing said porous polymeric material to body fluids.

66. (Amended) A kit comprising, in at least a first suitable container, at least a first nucleic acid segment and a structural matrix, wherein at least a portion of said structural matrix is a structural, porous alginate or modified alginate matrix or a structural matrix comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

67. The kit of claim 66, wherein said at least a first nucleic acid segment and said structural matrix are physically associated within a single container.

68. (Amended) An implantable device comprising at least a first nucleic acid segment in association with a structural matrix, wherein at least a portion of said structural matrix is a structural, porous alginate or modified alginate matrix or a structural matrix comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

102. (New) The kit of claim 66, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

103. (New) The implantable device of claim 68, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.



EXHIBIT B
PENDING CLAIMS
U.S. SERIAL NO. 09/442,542 (4100.002000; UM 1522p1)

1. (Amended) A composition comprising at least a first nucleic acid segment in association with a structural matrix, wherein:
 - (a) at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer; or
 - (b) at least a portion of said structural matrix is [an] a porous alginate or modified alginate matrix.
2. The composition of claim 1, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.
3. The composition of claim 2, wherein at least a portion of said structural matrix is comprised of a porous polymer that has an open pore structure.
4. The composition of claim 3, wherein at least a portion of said structural matrix is comprised of a porous polymer that has an interconnected pore structure.
5. The composition of claim 2, wherein said structural matrix consists essentially of a porous polymer that has an open pore structure.
6. The composition of claim 2, wherein said structural matrix comprises at least a first matrix portion comprised of said porous polymer integrally connected to at least a second matrix portion comprised of an impermeable polymer.
7. The composition of claim 6, wherein said at least a first matrix portion is comprised of a porous polymeric material that has a substantially uniform open pore structure, and wherein said at least a second matrix portion is comprised of the same polymeric material in a form that lacks an open pore structure.
8. The composition of claim 2, wherein said structural matrix is a biocompatible matrix.

9. The composition of claim 2, wherein said structural matrix is a biodegradable matrix.
10. The composition of claim 2, wherein said structural matrix is a biocompatible and biodegradable matrix.
11. The composition of claim 2, wherein at least a portion of said structural matrix is comprised of a lactic acid polymer, glycolic acid polymer or lactic acid/glycolic acid copolymer matrix.
12. The composition of claim 11, wherein at least a portion of said structural matrix is comprised of a lactic acid/glycolic acid (PLGA) copolymer matrix.
13. (Amended) The composition of claim 1, wherein at least a portion of said structural matrix is [an] a porous alginate or modified alginate matrix.
14. The composition of claim 13, wherein at least a portion of said structural matrix is a modified alginate matrix that comprises at least one alginate chain section bonded to at least one molecule that mediates cellular interactions.
15. The composition of claim 14, wherein at least a portion of said structural matrix is a modified alginate matrix that comprises at least one alginate chain section bonded to at least one cellular interaction molecule selected from the group consisting of cell adhesion molecules, cell attachment peptides, proteoglycan attachment peptide sequences, proteoglycans, cell adhesion polysaccharides, growth factors and cell adhesion enzymes.
16. The composition of claim 15, wherein at least a portion of said structural matrix is a modified alginate matrix that comprises at least one alginate chain section bonded to at least one cellular interaction molecule selected from the group consisting of an RGD peptide, fibronectin, vitronectin, Laminin A, Laminin B1, Laminin B2, collagen 1 and thrombospondin.
17. The composition of claim 13, wherein at least a portion of said structural matrix is a modified alginate matrix prepared by a method comprising:
 - (a) providing a solution of a hydrogel-forming material and a surfactant;
 - (b) mixing said solution in the presence of a gas to form a stable foam;

- (c) exposing said stable foam to conditions or agents that result in gelling of the hydrogel-forming material and in the generation of gas bubbles therein; and
- (d) exposing the hydrogel containing gas bubbles to a vacuum to release the gas and form the hydrogel material having macroporous open pore porosity.

18. The composition of claim 13, wherein at least a portion of said structural matrix is a modified alginate matrix prepared by a method comprising:

- (a) providing a solution of a hydrogel-forming material, a surfactant and a gas-generating component, wherein said solution is capable of being mixed in the presence of a gas to incorporate the gas in the solution and form a stable foam;
- (b) mixing said solution in the presence of a gas to form a stable foam;
- (c) exposing said stable foam to conditions or agents that result in gelling of the hydrogel-forming material and to conditions or agents that result in generation of gas from the gas-generating component, to form a hydrogel containing gas bubbles therein; and
- (d) exposing said hydrogel containing gas bubbles therein to a vacuum to release the gas and to form the hydrogel material having macroporous open pore porosity.

19. The composition of claim 1, wherein said nucleic acid segment is a DNA molecule.

20. The composition of claim 1, wherein said nucleic acid segment is an antisense nucleic acid molecule or a ribozyme.

21. The composition of claim 1, wherein said nucleic acid segment is comprised within a plasmid or a recombinant expression vector.

22. The composition of claim 21, wherein said nucleic acid segment is operatively positioned downstream from a promoter within a recombinant viral expression vector.

23. The composition of claim 22, wherein said nucleic acid segment is operatively positioned downstream from a promoter within a recombinant adenovirus, a recombinant adeno-associated virus (AAV) or a recombinant retrovirus.

24. The composition of claim 21, wherein said nucleic acid segment encodes a protein or polypeptide.

25. The composition of claim 24, wherein said nucleic acid segment encodes a marker protein.

26. The composition of claim 24, wherein said nucleic acid segment encodes a protein or polypeptide that stimulates a bone progenitor cell when expressed in said cell.

27. The composition of claim 24, wherein said nucleic acid segment encodes a protein or polypeptide that stimulates a wound healing fibroblast, granulation tissue fibroblast or repair cell when expressed in said cell.

28. The composition of claim 24, wherein said nucleic acid segment encodes an antigenic or immunogenic protein or polypeptide that stimulates an immune response when expressed by an antigen presenting cell.

29. The composition of claim 24, wherein said nucleic acid segment encodes a cytotoxic or apoptosis-inducing protein or polypeptide that induces cell death upon expression in a cell.

30. The composition of claim 24, wherein said nucleic acid segment encodes a transcription or elongation factor, cell cycle control protein, kinase, phosphatase, DNA repair protein, oncogene, tumor suppressor, angiogenic protein, anti-angiogenic protein, immune response stimulating protein, cell surface receptor, accessory signaling molecule, transport protein, enzyme, anti-bacterial or anti-viral protein or polypeptide.

31. The composition of claim 24, wherein said nucleic acid segment encodes a hormone, neurotransmitter, growth factor, growth factor receptor, interferon, interleukin, chemokine, cytokine, colony stimulating factor or chemotactic factor protein or polypeptide.

32. The composition of claim 31, wherein said nucleic acid segment encodes a growth hormone (GH) protein or polypeptide, a parathyroid hormone (PTH) protein or polypeptide, a PTH1-34 polypeptide or a bone morphogenetic protein (BMP) protein or polypeptide.

33. The composition of claim 32, wherein said nucleic acid segment encodes a BMP-2A, BMP-2B, BMP-3, BMP-4, BMP-5, BMP-6, BMP-7 or BMP-8 protein or polypeptide.

34. The composition of claim 31, wherein said nucleic acid segment encodes a transforming growth factor- α (TGF- α), TGF- β 1 or TGF- β 2 protein or polypeptide, a latent TGF β binding protein (LTBP) protein or polypeptide, an activin/inhibin protein or polypeptide, a fibroblast growth factor (FGF), a granulocyte/macrophage colony stimulating factor (GMCSF), an epidermal growth factor (EGF), a platelet derived growth factor (PDGF), an insulin-like growth factor (IGF) or a leukemia inhibitory factor (LIF).

35. The composition of claim 24, wherein said nucleic acid segment encodes a human protein or polypeptide.

36. The composition of claim 1, comprising at least a first and second nucleic acid segment.

37. The composition of claim 1, comprising a plurality of nucleic acid segments.

38. The composition of claim 1, further comprising a population of cells.

39. The composition of claim 38, wherein at least a portion of said nucleic acid segment is taken up by the cells comprised within said composition.

40. The composition of claim 1, prepared by admixing at least a first nucleic acid segment with said structural matrix.

41. The composition of claim 2, prepared by a process that comprises leaching out the particulate material from a composition comprising a gas foamed polymeric material, at least a first nucleic acid segment and a leachable particulate material.

42. The composition of claim 2, prepared by a process that comprises the steps of:

- (a) preparing an admixture comprising at least a first nucleic acid segment, particles capable of forming a polymeric structure and a leachable particulate material;
- (b) subjecting said admixture to a gas foaming process to create a porous polymeric structure that comprises said at least a first nucleic acid segment and said leachable particulate material; and

- (c) subjecting said porous polymeric structure to a leaching process that removes said leachable particulate material from said porous polymeric structure, thereby producing a polymeric structure of additional porosity that comprises said at least a first nucleic acid segment.

43. The composition of claim 42, wherein said admixture comprises said at least a first nucleic acid segment, beads or microspheres capable of forming a polymeric structure and said leachable particulate material.

44. The composition of claim 43, wherein said at least a first nucleic acid segment is incorporated within said beads or microspheres prior to said admixing or gas foaming steps.

45. The composition of claim 42, wherein said leaching process is conducted *in vitro* by subjecting said porous polymeric material to a leaching agent.

46. The composition of claim 42, wherein said leaching process is conducted *in vivo* by exposing said porous polymeric material to body fluids.

47. A composition comprising at least a first nucleic acid segment in non-covalent association with a structural matrix, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

48. (Amended) A composition comprising at least a first nucleic acid segment in non-covalent association with a structural, porous alginate or modified alginate matrix.

49. A composition comprising at least a first nucleic acid segment in association with a structural matrix, said structural matrix comprising at least a first matrix portion comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer, wherein said first matrix portion is integrally connected to a second matrix portion comprised of an impermeable polymer.

50. The composition of claim 49, wherein said first and second matrix portions are comprised of the same polymeric material, separately fabricated to form a first, porous polymer having a uniform open pore structure and a second, impermeable polymer lacking an open pore structure.

51. The composition of claim 49, wherein said first and second matrix portions are comprised of different polymeric materials.

52. An admixture, comprising at least a first nucleic acid segment; beads or microspheres of a polymer capable of forming a gas-foamed polymeric structure; and a leachable particulate material.

53. The admixture of claim 52, wherein said at least a first nucleic acid segment is incorporated within said beads or microspheres.

54. A method for making a structural matrix-nucleic acid composition, comprising providing at least a first nucleic acid segment to a structural matrix, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

55. The method of claim 54, comprising leaching out the particulate material from a composition comprising a gas foamed polymeric material, at least a first nucleic acid segment and a leachable particulate material.

56. The method of claim 55, comprising the steps of:

- (a) preparing an admixture comprising at least a first nucleic acid segment, particles of a polymeric material capable of forming a gas foamed polymeric structure and a leachable particulate material;
- (b) subjecting said admixture to a gas foaming process to create a porous polymeric structure that comprises said at least a first nucleic acid segment and said leachable particulate material; and
- (c) subjecting said porous polymeric structure to a leaching process that removes said leachable particulate material from said porous polymeric structure, thereby producing a polymeric structure of additional porosity that comprises said at least a first nucleic acid segment.

57. The method of claim 56, wherein said admixture is prepared by first incorporating said at least a first nucleic acid segment within said particles of a polymeric material and then admixing with said leachable particulate material.

58. The method of claim 57, wherein said admixture is prepared by first incorporating said at least a first nucleic acid segment within polymer beads or microspheres and then admixing with said leachable particulate material.

59. The method of claim 56, wherein the gas foaming process of step (b) comprises subjecting said admixture to an elevated pressure atmosphere of an inert gas in a manner effective to dissolve said gas into said polymeric material, and subjecting the gas-dissolved polymeric material to thermodynamic instability in a manner effective to cause nucleation and growth of gas pores sufficient to produce a continuous matrix of polymeric material that comprises said at least a first nucleic acid segment and said leachable particulate material.

60. The method of claim 59, wherein said thermodynamic instability is created by reducing said elevated pressure atmosphere.

61. The method of claim 56, wherein said leachable particulate material is a water-soluble leachable particulate material.

62. The method of claim 61, wherein said leachable particulate material is a salt, sugar or sugar alcohol.

63. The method of claim 62, wherein said leachable particulate material is NaCl, trehalose, glucose, sucrose or mannitol.

64. The method of claim 56, wherein said leaching process is conducted *in vitro* by contacting said porous polymeric material with a leaching agent.

65. The method of claim 56, wherein said leaching process is conducted *in vivo* by exposing said porous polymeric material to body fluids.

66. (Amended) A kit comprising, in at least a first suitable container, at least a first nucleic acid segment and a structural matrix, wherein at least a portion of said structural matrix is a structural, porous alginate or modified alginate matrix or a structural matrix comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

67. The kit of claim 66, wherein said at least a first nucleic acid segment and said structural matrix are physically associated within a single container.

68. (Amended) An implantable device comprising at least a first nucleic acid segment in association with a structural matrix, wherein at least a portion of said structural matrix is a structural, porous alginate or modified alginate matrix or a structural matrix comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

102. (New) The kit of claim 66, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.

103. (New) The implantable device of claim 68, wherein at least a portion of said structural matrix is comprised of a porous polymer that contains pores formed by gas foaming and pores formed by leaching out of a particulate from the polymer.